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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,978	02/14/2002	Ken Hassen	219671US0CONT	6080

22850 7590 11/29/2002

OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,978

Applicant(s)

HASSEN, KEN

Examiner

Susan Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time, Amendment, and Information Disclosure Statement filed 11/04/02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza U.S. 4,602,039 ('039), in view of Cavazza US 6,063,820 ('820).

Cavazza '039 teaches pharmaceutical composition in the form of tablet or capsule comprising salts of L-carnitine and salts of alkanoyl L-carnitine (see abstract, and claims 1-2). Cavazza '039 also teaches non-hygroscopic salts of L-carnitine as the active agent, which further comprises pharmaceutically acceptable excipients (column 7, lines 29-55). The methods of preparation are disclosed in examples 1-10.

Cavazza '039 does not teach the L-carnitine further comprising hydroxycitric acid, co-enzyme Q10, chromium picolinate, gamma linolenic acid, resveratrol, omega-3 acids, an antioxidant, or a vitamin.

Cavazza '820 teaches pharmaceutical composition comprising alkanoyl L-carnitine or pharmaceutically acceptable salt thereof, and gamma linolenic acid or salt thereof (column 2, lines 27-49). The composition may further comprises vitamins, co-

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enzymes, co-enzyme Q10, and antioxidants (columns 2-3). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to combine the teachings of '039 and the '820 by including additional ingredients such as gamma linolenic acid, vitamins, co-enzymes, and/or antioxidants into a pharmaceutical composition comprising hygroscopic salts of L-carnitine and alkanoyl L-carnitine with the expectation of at least similar result.

The examiner notes that the cited references do not teach the claimed particle sieve size, however, because they teach the crystallization of L-carnitine salts, and the manufacture of solid dosage forms using the crystallized product, the burden is shifted to the applicant to show criticality in the specific particle sieve size claimed.

Response to Arguments

Applicant's arguments filed 11/04/02 have been fully considered but they are not persuasive. The examiner maintains the original rejection.

Applicant argues that the cited references provide no teaching which would suggest the presently claimed ultrafine L-carnitine. However, the claiming of L-carnitine that can be sieved through 100 USBS mesh sieve does not establish the range of particle size, which can lead to the allege that Cavazza does not teach the claimed particle size. The crystalline L-carnitine could have been so fine or may be not ultrafine, but might have been in the particle size range that can be sieved through 100 USBS mesh. Accordingly, absent showing evidence on the contrary, no criticality is seen in the particular sieve size, since Cavazza recognizes the properties required by the applicant, composition comprising L-carnitine and its' salts that can be easily

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compounded and are favorably suitable for manufacturing solid administration forms (see abstract, '039).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

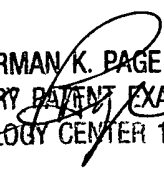
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600